

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Suzanne Klimberg et al.

Title: IMPROVED TREATMENT OF CANCER WITH GLUTAMINE

Docket No.: 781.020US1

Serial No.: 10/633,402

Filed: August 1, 2003

Due Date: N/A

Examiner: Kevin E. Weddington

Group Art Unit: 1614

MS Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

☒ A return postcard.

☒ A Supplemental Information Disclosure Statement (2 pgs.), Form 1449 (3 pgs.), and copies of 40 cited documents.

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

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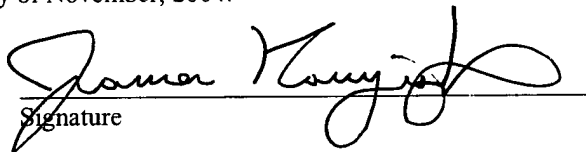
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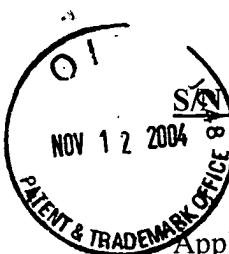
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JAMES KANYUSIK  
Name

  
Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

(GENERAL)



S/N 10/633,402

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	V. Suzanne Klimberg et al.	Examiner:	Kevin E. Weddington
Serial No.:	10/633,402	Group Art Unit:	1614
Filed:	August 01, 2003	Docket:	781.020US1
Title:	IMPROVED TREATMENT OF CANCER WITH GLUTAMINE		

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Supplemental Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Supplemental Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Supplemental Information Disclosure Statement considered.

The present application is a U.S. national patent application filed after June 30, 2003. Thus, Applicant believes that the U.S. Patent & Trademark Office has waived the requirement under 37 C.F.R. 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication. The waiver is provided in a pre-OG notice from the U.S. Patent & Trademark Office entitled "Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003" and dated July 11, 2003. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.


Respectfully submitted,

V. SUZANNE KLIMBERG ET AL.

By their Representatives,

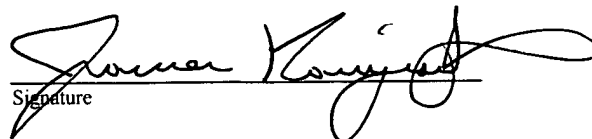
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
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Date 11-9-04

By   
Warren D. Woessner  
Reg. No. 30,440

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Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)	Complete if Known	
	Application Number	10/633,402
	Filing Date	August 1, 2003
	First Named Inventor	Klimberg, V.
	Group Art Unit	1614
	Examiner Name	Weddington, Kevin
Sheet 1 of 3		Attorney Docket No: 781.020US1

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
	US-2,283,817	05/19/2042	Martin, G. J., et al.	167	55	05/24/1941
	US-2,868,693	01/13/1959	Shive, W. , et al.	167	55	07/16/1956
	US-4,857,555	08/15/1989	Smith, R. J.	514	563	09/12/1986
	US-5,039,704	08/13/1991	Smith, R. J., et al.	514	563	10/24/1988
	US-5,366,723	11/22/1994	Tulok, I.	424	10	03/05/1993
	US-5,397,803	03/14/1995	Smith, Robert J., et al.	514	563	04/26/1993
	US-5,607,975	03/04/1997	Smith, Robert J., et al.	514	563	05/07/1996
	US-5,684,045	11/04/1997	Smith, Robert J., et al.	514	563	05/07/1996
	US-5,763,485	06/09/1998	Smith, Robert J., et al.	514	563	03/13/1995

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ALVERDY, J C., "Effects of Glutamine-Supplemented Diets on Immunology of the Gut", <u>Journal of Parenteral &amp; Enteral Nutrition</u> , 14(4) (Supp), (1990),109S-113S	
		ALVERDY, J C., "Parenteral Nutrition Results in Bacterial Translocation from the Gut and Death Following Chemotherapy", <u>14th Clinical Congress Abstracts</u> , 14 (1)(Supp), (1990), Page 8S	
		AMERICAN COLLEGE OF PHYSICIANS, "Parenteral Nutrition in Patients Receiving Cancer Chemotherapy", <u>Annals of Internal Medicine</u> , 110(9), (1989), 734-736	
		BROWN, M G., "Glutamine-enhanced Enteral Diet Improves Nitrogen Balance Without Increasing Portal Ammonia", <u>British Journal of Surgery</u> , 78(11), (1991),1305-1306	
		BURKE, D J., "Effect of Route of Glutamine Administration GM Mortality Following Experimental Enterocolitis", <u>14th Clinical Congress Abstracts</u> , 14(1) (Supp), (1991),1 Page	
		BURKE, D. J., "Glutamine-Supplemented Total Parenteral Nutrition Improves Gut Immune Function", <u>Archives of Surgery</u> , 124(12), (1989),1396-9	
		DECHELOTTE, P., "Absorption and Metabolic Effects of Enterally Administered Glutamine in Humans", <u>Journal of Physiology</u> , 260(5)(Pt 1), (1991),G677-G682	
		DEFERRARI, G., "Splanchnic Exchange of Amino Acids After Amino Acid Ingestion in Patients with Chronic Renal Insufficiency", <u>American Journal of Clinical Nutrition</u> , 48(1), (1988),72-83	
		EVANS, M. A., "Intestinal Fuels: Glutamine, Short-Chain Fatty Acids, and Dietary Fiber", <u>Journal of the American Dietetic Association</u> , 92(10), (1992),1239-1246	

EXAMINER

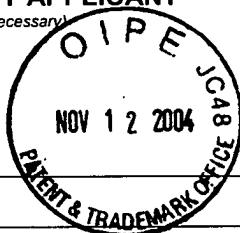
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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)



Complete if Known

<b>Application Number</b>	10/633,402
<b>Filing Date</b>	August 1, 2003
<b>First Named Inventor</b>	Klimberg, V.
<b>Group Art Unit</b>	1614
<b>Examiner Name</b>	Weddington, Kevin

Sheet 2 of 3

Attorney Docket No: 781.020US1

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		FISCHER, J. E., "Adjuvant Parenteral Nutrition in the Patient with Cancer", <u>Surgery</u> , 96(3), (1984),578-580	
		FISCHER, J. E., "Total Parenteral Nutrition, Glutamine, and Tumor Growth", <u>Jpn: Journal of Parenteral &amp; Enteral Nutrition</u> , 14(4) (Supp), (1990),86S-88S	
		FONG, Y. M., "Total Parenteral Nutrition and Bowel Rest Modify the Metabolic Response to Endotoxin in Humans", <u>Annals of Surgery</u> , 210(4), (1989),449-457	
		FOX, A. D., "Effect of a Glutamine-Supplemented Enteral Diet on Methotrexate-Induced Enterocolitis", <u>Journal of Parenteral &amp; Enteral Nutrition</u> , 12(4), (1988),325-331	
		FOX, A. D., "Reduction of the Severity of Enterocolitis by Glutamine-Supplemented Enteral Diets", <u>Surgical Forum</u> , 38, (1987),43-44	
		JACOBS, D. O., "Combined Effects of Glutamine and Epidermal Growth Factor on the Rat Intestine", <u>Surgery</u> , 104(2), (1988),358-364	
		JACOBS, D. O., "Disparate Effects Of 5-Fluorouracil On The Ileum And Colon Of Enterally Fed Rats With Protection By Dietary Glutamine", <u>Surgical Forum</u> , 38, (1987),45-46	
		KLIMBERG, V. S., "Oral Glutamine Accelerates Healing of the Small Intestine and Improves Outcome After Whole Abdominal Radiation", <u>Archives of Surgery</u> , 125(8), (1990),1040-1045	
		KLIMBERG, V. S., "Prophylactic Glutamine Protects the Intestinal Mucosa from Radiation Injury", <u>Cancer</u> , 66(1), (1990),62-68	
		MOORE, F. A., "TEN Versus TPN Following Major Abdominal Trauma - Reduced Septic Morbidity", <u>The Journal of Trauma</u> , 29(7), (1989),916-923	
		O'DWYER, S. T., "5-Fluorouracil Toxicity on Small Intestinal Mucosa But Not White Blood Cells is Decreased by Glutamine", <u>Clinical Research</u> , 35(3), (1987),Page 369A	
		O'DWYER, S. T., et al., "Chapter 28 - New Fuels for the Gut", In: <u>Clinical Nutrition - Enteral and Tube Feeding</u> , 2nd Edition, Rombeau, J. L., et al., editors, W. B. Saunders Company, (1990),540-555	
		PARRY-BILLINGS, M., "Does Glutamine Contribute to Immunosuppression After Major Burns?", <u>The Lancet</u> , 336(8714), (1990),523-525	
		ROMBEAU, J. L., "A Review of the Effects of Glutamine-Enriched Diets on Experimentally Induced Enterocolitis", <u>Journal of Parenteral &amp; Enteral Nutrition</u> , 14(4) (Supp), (1990),100S-105S	
		SCHLOERB, P. R., et al., "Total Parenteral Nutrition With Glutamine in Bone Marrow Transplantation and Other Clinical Applications (A Randomized, Double-Blind Study)", <u>Journal of Parenteral and Enteral Nutrition</u> , 17,5, (1993),407-413	
		SHOU, J., "Dietary Manipulation of Methotrexate-Induced Enterocolitis", <u>Journal of Parenteral &amp; Enteral Nutrition</u> , 15(3), (1991),307-312	
		SMITH, R. J., "Glutamine Nutrition and Requirements", <u>Journal of Parenteral &amp; Enteral Nutrition</u> , 14(4) (Supp), (1990),94S-99S	

**EXAMINER****DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional) <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached

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	<b>First Named Inventor</b>	Klimberg, V.
	<b>Group Art Unit</b>	1614
	<b>Examiner Name</b>	Weddington, Kevin
Sheet 3 of 3	Attorney Docket No: 781.020US1	

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		SOUBA, W. W., "Glutamine Nutrition in the Management of Radiation Enteritis", <u>Journal of Parenteral &amp; Enteral Nutrition</u> , 14(4) (Supp), (1990),106S-108S	
		SOUBA, W. W., "Glutamine Nutrition: Theoretical Considerations and Therapeutic Impact", <u>Journal of Parenteral &amp; Enteral Nutrition</u> , 14(5) (Supp), (1990),237S-243S	
		SOUBA, W. W., "Intestinal Consumption of Intravenously Administered Fuels", <u>Journal of Parenteral &amp; Enteral Nutrition</u> , 9(1), (1985),18-22	
		SOUBA, W. W., "Oral Gutamine Reduces Bacterial Translocation Following Abdominal R.adiation", <u>Journal of Surgical Research</u> , 48(1), (1990),1-5	
		SOUBA, W. W., "The Gut as a Nitrogen-Processing Organ in the Metabolic Response to Critical Illness", <u>Nutrition Support Services</u> , 8, (1988),15-22	
		STEIGER, E., "Effects of Nutrition on Tumor Growth and Tolerance to Chemotherapy", <u>Journal of Surgical Research</u> , 18(4), (1975),455-66	
		VAN ZAAANEN, H. C. T. , et al., "Parenteral Glutamine Dipeptide Supplementation Does Not Ameliorate Chemotherapy-Induced Toxicity", <u>Cancer</u> , 74(10), (1994),2879-2884	
		VANDERHOOF, J. A., "Effects of Oral Supplementation of Glutamine on Small Intestinal Mucosal Mass Following Resection", <u>Journal of the American College of Nutrition</u> , 11(2), (1992),223-227	
		WELLS, C. L., "The Effect of Dietary Glutamine and Dietary RNA on Ileal Flora, Ileal Histology, and Bacterial Translocation in Mice", <u>Nutrition</u> , 6(1), (1990),70-83	
		WINDMUELLER, H. G., "Glutamine Utilization by the Small Intestine", <u>Advances in Enzymology &amp; Related Areas of Molecular Biology</u> , 53, (1982),201-37	
		WINDMUELLER, H. G., "Intestinal Metabolism of Glutamine and Glutamate from the Lumen as Compared to Glutamine from Blood", <u>Archives of Biochemistry &amp; Biophysics</u> , 171(2), (1975),662-672	
		WINDMUELLER, H. G., "Respiratory Fuels and Nitrogen Metabolism <i>In Vivo</i> in Small Intestine of Fed Rats. Quantitative importance of glutamine, glutamate, and aspartate", <u>Journal of Biological Chemistry</u> , 255(1), (1980),107-112	
		ZIEGLER, T. R., "Clinical and Metabolic Efficacy of Glutamine-Supplemented Parenteral Nutrition After Bone Marrow Transplantation. A Randomized, Double-Blind, Controlled Study", <u>Annals of Internal Medicine</u> , 116(10), (1992),821-828	
		ZIEGLER, T. R., "Safety and Metabolic Effects of L-Glutamine Administration in Humans", <u>Journal of Parenteral &amp; Enteral Nutrition</u> , 14(4 Suppl), (1990), 137S-146S	

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